



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-N-1428]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Guidance for Industry on Electronic Drug Product Reporting of Human Drug Compounding Outsourcing Facilities Under Section 503B of the Federal Food, Drug, and Cosmetic Act

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202-395-7285, or emailed to [oir\\_submission@omb.eop.gov](mailto:oir_submission@omb.eop.gov). All comments should be identified with the title. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, Three White Flint North, 10A63, 11601 Landsdown Street, North Bethesda, MD 20852, [PRASStaff@fda.hhs.gov](mailto:PRASStaff@fda.hhs.gov).

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Guidance for Industry: Electronic Product Reporting for Human Drug Compounding  
Outsourcing Facilities Under Section 503B of the Federal Food, Drug, and Cosmetic Act;  
Availability--

OMB Control Number 0910--(NEW)

On November 27, 2013, the President signed the Drug Quality and Security Act (DQSA) into law (Pub. L. 113-54). The DQSA added a new section 503B to the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 353b). Under section 503B(b), a compounder can register as an outsourcing facility with FDA. If the conditions outlined in section 503B(a) of the FD&C Act are satisfied, a drug compounded by or under the direct supervision of a licensed pharmacist in an outsourcing facility is exempt from certain sections of the FD&C Act, including section 502(f)(1) (21 U.S.C. 352(f)(1)) (concerning the labeling of drugs with adequate directions for use) and section 505 (21 U.S.C. 355) (concerning the approval of human drug products under new drug applications or abbreviated new drug applications). Drugs compounded in outsourcing facilities are not exempt from the requirements of section 501(a)(2)(B) of the FD&C Act (21 U.S.C. 351(a)(2)(B)) (concerning current good manufacturing practice for drugs).

In the Federal Register of November 24, 2014 (79 FR 69857), FDA announced the availability of a revised draft guidance for industry entitled “Electronic Drug Product Reporting for Human Drug Compounding Outsourcing Facilities Under Section 503B of the Federal Food, Drug, and Cosmetic Act.” Under section 503B of the FD&C Act, and as described in the revised draft guidance, an outsourcing facility must, at the time of initial registration and twice each year, in June and December, submit to FDA a report identifying the drugs compounded by the

facility during the previous six-month period. For each identified drug, the outsourcing facility must provide certain information, which is listed in section 503B(b)(2)(A)(ii) of the FD&C Act and in the revised draft guidance.

Each facility that elects to register as an outsourcing facility must report the following information to FDA for each product that it compounds:

- The active ingredient and strength of active ingredient per unit;
- the source of the active ingredient (bulk or finished drug);
- the National Drug Code (NDC) number of the source drug or bulk active ingredient, if available;
- the dosage form and route of administration;
- the package description;
- the number of individual units produced; and
- the NDC number of the final product, if assigned.

Compounded product information must be submitted to FDA electronically using the Structured Product Labeling (SPL) format and in accordance with section IV of the FDA guidance entitled “Providing Regulatory Submissions in Electronic Format--Drug Establishment Registration and Drug Listing,” available at <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm064994.htm>. Under the revised draft guidance, outsourcing facilities may request a waiver from the SPL electronic submission process by submitting a written request to FDA explaining why the use of electronic means is not reasonable for the person requesting the waiver.

In response to the November 24, 2014, Federal Register notice, FDA received three comments on the revised draft guidance. Comments that addressed the information collection provisions are identified and discussed here.

One comment expressed concern about being unable to submit a product report within the required 30-day reporting period because of the extensive amount of time to create a product report, especially for facilities with large product portfolios. The comment suggested that FDA did not recognize that each outsourcing facility will have numerous SPL entries into the electronic reporting system to make up a product report.

In consideration of the comment, we have increased our burden estimate as reflected in the tables 1 and 2. We have also explained in the guidance that there are ways to simplify the submission of product reporting information and reduce the number of responses and total burden of submitting product reporting information.

Initially, the creation of product report submissions can be time consuming, but submissions can be saved, updated, and resubmitted for subsequent reporting periods instead of creating a new submission each time. In addition, multiple strengths of the same drug, package sizes, and source NDC numbers can be consolidated into a single product submission in SPL.

Based on current data for outsourcing facilities, we estimate approximately 55 outsourcing facilities will submit to FDA an initial report identifying all drugs compounded in the facility in the previous 6 months. By our calculation, each product's SPL submission is considered a separate response and therefore each facility's product report will include multiple responses. Taking into account that a particular product that is compounded into different strengths from different sources of active ingredient can be reported in a single SPL response, we

estimate that the number of products reported per facility will average 220 products per facility. This estimate is based on current data in product reports.

Concerning the comment that each outsourcing facility will have numerous SPL entries, again we have revised our previous estimate to account for the fact that each product report will consist of multiple SPL responses per facility. We estimate that preparing and submitting this information electronically could take up to approximately 2 hours for each initial SPL response.

We also estimate that approximately 55 outsourcing facilities will submit to FDA a report twice each year identifying all drugs compounded at the facility in the previous 6 months. As described previously, we estimate on average 220 SPL responses per facility. We estimate that preparing and submitting this information electronically will take approximately one half hour per response. At the same time, we have reduced the burden for semi-annual product submissions reasoning that outsourcing facilities can save each SPL response once initially created and submitted. For subsequent reports, an outsourcing facility may resubmit the same file(s) after changing only the following data elements to appropriate values for the reporting period (along with other data as appropriate): RootID and version number (both SPL metadata); effective date (to identify the reporting period); and the number of units produced. Furthermore, if a product was not compounded during a particular reporting period, no SPL response needs be sent for that product during that reporting period.

Finally, we expect to receive no more than one waiver request from the electronic submission process for initial product reports and semi-annual reports, and estimate each request will take 1 hour to prepare and submit to FDA.

Therefore, we estimate the burden of this collection of information as follows:

Table 1.--Estimated Initial Reporting Burden<sup>1</sup>

Information Collection Activity	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
Submission of Initial Product Report	55	220	12,100	2	24,200
Waiver Request From Electronic Submission of Initial Product Report	1	1	1	1	1
Total					24,201

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with the information collection.

Table 2.--Estimated Annual Reporting Burden<sup>1</sup>

Information Collection Activity	No. of Respondents	Number of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
Submission for June Product Report	55	220	12,100	0.5 (30 minutes)	6,050
Submission for December Product Report	55	220	12,100	0.5 (30 minutes)	6,050
Waiver Request From Electronic Submission of Product Reports	1	1	1	1	1
Total					12,101

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with the information collection.

Dated: July 26, 2016.

Jeremy Sharp,

Deputy Commissioner for Policy, Planning, Legislation, and Analysis

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